McLaren HEALTH CARE		Policy Title:	Review and Management of Conflict of Interest in Research
Effective Date:	March 14, 2013	**Policy Number:**	MHC_RP0203
Review Date:	August 18, 2020	**Section:**	Human Research Protections Program (HRPP)
Revised Date:	March 22, 2024	**Oversight Level:**	Corporate
Administrative Responsibility:	Institutional Official, HRPP Corporate Manager of Research Integrity		

1. Purpose

1.1. The purpose of this policy is:

1.1.1. To describe the functions and responsibilities of the Research Conflict of Interest Committee (RCOI).

1.1.2. Assure compliance with Both PHS and FDA federal regulations regarding conflict of interest.

1.1.3. To set forth principles, policies, and procedures to identify financial conflicts of interest and to eliminate or mitigate the potential adverse effects of such conflicts on the rights and welfare of participants and the objectivity with which a research study is designed, conducted and/or reported.

1.1.4. The purpose of this policy is to ensure an individual's significant financial interests do not jeopardize the objectivity of research conducted at MHC.

1.1.5. To describe the investigator's responsibility to disclose any financial interests related to their institutional responsibilities including their key research personnel and family members.

2. Scope

2.1. This policy applies to all individuals, investigators and research personnel involved in research projects that are:

2.1.1. Submitted to and overseen by the McLaren Health Care Corporate Institutional Review Board (MHC IRB).

2.1.2. Make use of the space, facilities, materials, personnel, or other resources of McLaren Health Care.

3. Definitions

3.1. Refer to Appendix I *"Definitions"*

4. Policy

4.1. McLaren Health Care Corporation (MHC) is committed to conducting all research activities in accordance with the highest standards of integrity and ethics. It is MHC policy to preserve public trust in the integrity and quality of research at the organization by minimizing actual or perceived conflict to interest in the conduct of research.

4.2. This policy meets the requirements of and responsibilities for compliance with:

4.2.1. Regulations pertaining to federally funded research.

4.2.2. Accreditation standards of the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

4.2.3. FDA requirements for Financial Disclosure by investigators.

4.3. The Research Conflict of Interest Committee is given responsibility, on behalf of the organization, to review financial interest disclosures, identify financial conflicts of interest, and create management plans where appropriate.

4.3.1. This committee functions as a subcommittee of the Corporate Conflict of Interest Committee.

4.3.2. This committee is comprised of a cross section of corporate compliance and research representatives including but not limited to: Corporate Manager of Research, Corporate Compliance Officer, subsidiary compliance representative(s), IRB representative(s), Research Coordinator, etc.

4.4. An individual who is involved in the oversight, design, conduct, and/or reporting of research is required to disclose to McLaren all financial interests (AND those of his/her spouse, dependent children and research personnel) that are related to the institutional responsibilities.

4.5. An individual who is involved in the oversight, design, conduct, and/or reporting of research must adhere to this policy and management plan issued by the Research Conflict of Interest Committee.

4.5.1. The Research Conflict of Interest Committee is given the responsibility, on behalf of the organization, to review financial interest disclosures, identify financial conflicts of interest and create a management plan where appropriate.

4.5.2. These actions may involve referral to appropriate advisors outside the facility or obtaining advice from McLaren Health Care legal counsel.

4.6. If used, outside advisors will be individuals who have sufficient seniority, expertise, and independence to evaluate the competing interests at stake and to make credible and effective recommendations.

4.7. After reviewing a significant financial interest in research, the Research Conflict of Interest Committee will communicate its conclusions, along with any management arrangements to be imposed, to the MHC IRB.

4.8. All relevant conflicts will be disclosed to research participants in a form to be determined by the MHC IRB.

4.9. The IRB requires that all individuals involved in the design, conduct, or reporting of the research must report financial interests related to the research. Of note, in addition to principal investigators and co/sub- investigators, research personnel and individuals involved in the design, conduct, or reporting of the research may include personnel such as study coordinators, data coordinators, and other support staff Financial COI and management plans will be reported to Federal funding and regulatory agencies and to other funders as required.

5. Procedure

5.1. Disclosure of Requirements Investigator COI

5.1.1. Each investigator will be prompted annually to disclose financial interests in accordance with MHC's annual conflict of interest disclosure process and as described in *MHC_CC0137_Provider Conflict of Interest and Business Integrity* policy.

5.1.2. All investigators submitting protocols to the MHC IRB for review must submit a conflict-of-interest disclosure statement.

5.1.2.1. The investigator will be prompted to disclose financial interests when the application asks protocol-specific questions regarding conflict of interest for the investigators, personnel, and their immediate families.

5.1.3. All disclosures will be made electronically (to the extent possible).

5.2. Disclosure Requirements for research funded by agency that follows Public Health Services (PHS).

5.2.1. In addition to 5.1 Investigators involved in research funded by agency that follows Public Health Services (PHS) COI regulations must disclose travel when the aggregate value of sponsored or reimbursed travel exceeds an estimated $5,000 for an entity in the previous 12 months.

5.2.2. Travel for which the individual is reimbursed for by an outside entity.

5.2.3. Travel that is paid for on the individual's behalf by an outside entity.

5.2.4. Includes:

- the purpose
- identity of sponsor or organizer
- destination and duration
- any registration fees, accommodations, and transportation cost

5.2.5 Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

5.3. The IRB will notify RCOI Committee if an investigator discloses a financial interest in the IRB application.

5.4. Committee Review of Financial Interest Disclosure

5.4.1. All financial interest disclosures will be made available to the committee for review, in accordance with the requirements described below:

5.4.1.1. For each new project, the committee will review all financial interest disclosures before the project begins. Specifically, for PHS-funded research, the committee will review all financial interest disclosures before the expenditure of PHS funds.

5.4.2. For each financial interest, the committee will determine:

5.4.2.1. **Is the Financial Interest *related to* research?**

5.4.2.1.1. Financial interest is *related to* the research if the committee determines that the financial interest could be affected by the research.

5.4.2.1.2. Is in an entity whose financial interest could be affected by the research.

5.4.2.2. **If the Financial Interest is *related to* the research, does it constitute a Financial Conflict of Interest?**

5.4.2.2.1. A financial conflict of interest exists if the committee determines that the interest could *directly and significantly* affect the design, conduct, or reporting of the research. In making this determination, the Committee will consider—and may ask the Investigator to provide—additional information related to the following factors:

5.4.2.2.1.1. Nature of the interest (e.g., consulting, equity interest, speaking fee, travel, etc.).

5.4.2.2.1.2. Value or amount of financial interest.

5.4.2.2.1.3. The investigator's role in the project (e.g., consenting/enrolling patients, data analysis, publication & reporting, etc.)

5.4.2.2.1.4. Risk profile of the project (i.e., to project participants, to the organization, etc.).

5.4.2.2.1.5. Additional information regarding the relationship of financial interest to the research project or program.

5.4.3. The committee will contact the investigator to provide additional information, if necessary, to assist with the committee's review and determination.

5.4.4. The committee may also seek additional information from MHC, to determine whether the research could create any new intellectual property rights.

5.4.5. If the committee determines that no FCOI exists, The RCOI Committee shall inform the Investigator via a letter and the IRB analyst will forward letter to investigator and file letter with research protocol documents for IRB reviewer(s) to review.

5.4.6. If the committee determines that an FCOI exists, the committee will develop a management plan described in Section 5.4.

5.4.7. If the committee determines that an FCOI exists with respect to a PHS-funded research project, MHC Human Research Protections Program will report certain information to PHS, as required by Federal Regulations.

5.5. Management Plan of COI

5.5.1. A management plan related to an FCOI in research will be developed by the Committee and implemented before the research project begins.

5.5.2. A management plan may include, but is not necessarily limited to, the following:

5.5.2.1. Public disclosure of the FCOI (e.g., when presenting or publishing).

5.5.2.2. Disclosure of conflict to institutional committees, research, or program participants (e.g., through consent documents), and data safety monitoring boards.

5.5.2.3. Modification of the research protocol.

5.5.2.4. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research (e.g., cannot conduct data analysis, restricted from recruiting human subjects and/or conducting the informed consent process).

5.5.2.5. Reduction or elimination of the financial interest (e.g., divestiture or sale of an equity interest).

5.5.2.6. Severance of relationship(s) that create the financial interest.

5.5.2.7. Appointment of an independent monitor capable of taking measures (e.g., review of data) to protect the design, conduct and reporting of the research against bias resulting from the FCOI; and/or

5.5.2.8. Appointment of an independent monitor to review the consent process or the appropriateness of clinical care provided to research/program participants, if applicable.

5.5.3. In determining the management plan for an FCOI related to human subject research, the committee will consider, among other things, whether the Investigator will be allowed to participate in the following activities:

5.5.3.1. Subject recruitment.

5.5.3.2. Screening for inclusion/exclusion criteria.

5.5.3.3. The consent processes.

5.5.3.4. Clinical evaluation of subjects during the research.

5.5.3.5. Reporting of data; and/or

5.5.3.6. Conducting data analysis.

5.5.4. In general, the committee will permit the Investigator to participate in the foregoing activities only if *compelling circumstances* justify such participation.

5.5.5. Compelling circumstances may exist when, for example, the Investigator is the only individual at MHC with the expertise necessary to conduct certain study-related activities.

5.5.6. The management plan for an FCOI related to human subject research will be reported to the IRB:

5.5.6.1. The Research Integrity Manager will notify the IRB Chair and IRB Analyst via email.

5.5.6.2. IRB Analyst will place management plan for FCOI on the next convened IRB meeting agenda.

5.5.6.3. IRB Analyst will forward to each IRB member copy of protocol, financial disclosure, and management plan for FCOI.

5.5.7. The management plan for an FCOI related to human subject research will be reviewed by the MHC IRB before the research project begins.

5.5.8. The MHC IRB may:

5.5.8.1. Approve the management plan.

5.5.8.2. Make additional recommendations to the committee with respect to the Management Plan; or

5.5.8.3. Determine that the FCOI cannot be managed sufficiently to protect the rights, safety, and welfare of human subjects, in which case the MHC IRB and the committee will determine appropriate steps to be taken (e.g., the research may not be conducted at MHC and its subsidiary hospitals, the investigator may not be involved in the research study, or the investigator must eliminate his/her FCOI before the research can take place at MHC and/or its subsidiary hospitals).

5.5.9. The management plan may specify the steps to be taken to monitor and verify the Investigator's compliance with the plan (**Section 5.5.1, Monitoring of Compliance** below).

5.5.10. The management plan will be documented and must be reviewed and acknowledged by the Investigator.

5.5.10.1. Investigators submitting new studies for which they or any member of key personnel have been issued a conflict-of-interest management plan should ensure that all applicable COI requirements are reflected in the submission.

5.6. New Disclosures and Interim Management Plans

5.6.1. Investigators and research staff must disclose any new significant financial interests within 30 business days of acquisition or discovery.

5.6.2. If an investigator who is new to a research project discloses a financial interest OR if an existing investigator discloses a new financial interest, the committee will, within thirty (30) business days of the disclosure, review the financial interest and determine whether an FCOI exists; if so, the committee will develop and implement a management plan, on at least an interim basis.

5.6.3. In the case of PHS-funded research, the committee will also determine whether reporting to PHS is required.

5.6.4. Depending on the nature of the financial interest, the committee may determine that additional interim measures are necessary between the date of disclosure and completion of the committee's review.

5.6.5. If a financial interest was not disclosed by an investigator or, for whatever reason, was not previously reviewed by the committee, the committee will, within thirty (30) days of receipt of the disclosure, review the financial interest and related information and determine whether an FCOI exists. If so, the committee will develop and implement a management plan, on at least an interim basis. In the case of PHS-funded research, the committee will also determine whether reporting to PHS is required.

5.7. Compliance

5.7.1. Monitoring of Compliance

5.7.1.1. If the committee issues a management plan, the committee will monitor compliance with the plan until its completion, or until the completion of the research project to which the Investigator's FCOI relates.

5.7.1.2. The committee's monitoring activities may include annual or periodic investigator self-certification of compliance; review of investigator publications and presentations prior to issuance; or in-person meetings with the investigator to review steps taken to implement the plan.

5.7.2. Retrospective Review

5.7.2.1. Whenever there is noncompliance with the management plan, the committee will conduct a retrospective review to determine whether, during the period of noncompliance, the research project was biased in its design, conduct and/or reporting.

5.7.2.2. Noncompliance may include, but is not limited to, failure to timely identification or management of an FCOI; failure to disclose a financial interest

that the committee determines to be an FCOI; or failure to review or manage an FCOI.

5.7.2.3. The retrospective review will be completed within ninety (90) days of the Committee's determination of noncompliance.

5.7.2.4. The committee will determine the methodology for the review process, as well as the composition of the review panel and the documents to be reviewed.

5.7.2.5. The committee will document the results of the review.

5.7.3. **Corrective Action**

5.7.3.1. Depending on the nature of the FCOI, the committee may determine that additional interim measures are necessary with regard to the investigator's participation in the project between the date that the FCOI or the investigator's noncompliance is determined, and the completion of the committee's retrospective review.

5.7.3.2. Failure to disclose a financial COI or non-compliance with an application will result in corrective action, as determined by the IRB Corrective action may include, but is not limited to:

5.7.3.2.1. Completion of additional research education as determined by the oversight committee, Research Administration or PHS.

5.7.3.2.2. Restrictions on the use of data derived from the research. Suspension or termination of the research project.

5.7.3.2.3. Withdrawal of funding.

5.7.3.2.4. Loss of research privileges at MHC

5.7.3.2.5. Formal corrective action.

5.7.3.2.6. Report on actions to external regulatory agencies.

5.7.3.3. When non-compliance with a COI management plan related to a PHS funded project occurs, a retrospective review will be conducted. If bias in the research is found, a mitigation report will be filed with PHS and include:

5.7.3.3.1. Key elements documented in the retrospective review.

5.7.3.3.2. A description of the bias identified in the research.

5.7.3.3.3. The plan of action(s) to eliminate or mitigate the effect of the bias.

5.7.3.4. Failure of the investigator or Key Personnel to comply with the requirements of a management plan could result in:

5.7.3.4.1. Termination of the study, or in suspension of some or all study activities by either the MHC IRB in keeping with the MHC IRB Policy on Noncompliance

5.7.3.4.2. The MHC IRB may also recommend further corrective action based on applicable MHC policies and procedures (Human Resources, Medical Staff, Corporate Compliance, etc.).

5.7.3.5. Based on the results of the retrospective review, the committee will determine what action(s) will be taken to manage the FCOI going forward.

5.8. Reporting Requirements for PHS-funded research ONLY

5.8.1. If the committee determines that an FCOI exists, and it is related to PHS-funded research, the McLaren HRPP will report such FCOI to the PHS awarding component (e.g., National Institutes of Health) prior to the expenditure of any funds for the award (i.e., the "initial report").

5.8.2. For all new FCOI and all FCOI that are identified subsequent to the initial report (e.g., upon participation of an investigator who is new to the research project, or identification of an FCOI not previously disclosed), the McLaren HRPP will make the FCOI report to the PHS awarding component within sixty (60) days of identification or disclosure of the Financial Interest.

5.8.3. Each FCOI report will include sufficient information to enable the PHS awarding component to understand the nature and extent of the FCOI and to assess the appropriateness of the management Plan.

5.8.4. During the period of the PHS award, the McLaren HRPP will also submit an annual FCOI update. The annual update will include any changes in information regarding the previously disclosed financial interest (i.e., updated value of a previously disclosed equity interest) and any changes to the management plan.

5.8.5. Following the retrospective review, as described in Section 5.5.2. of this policy, the McLaren HRPP will submit an update to any previously submitted FCOI report including any mitigation plan, when/if applicable

5.9. Public Accessibility of Information for PHS-funded research ONLY

5.9.1. Information related to the FCOI of senior personnel for a PHS funded research project will be publicly accessible, so long as the financial interest is held by the senior personnel.

5.9.2. The McLaren HRPP will make this information available via a written response to any requestor within 5 business days of the request.

5.9.3. The written response will include, at a minimum, the following:

5.9.3.1. Project number.

5.9.3.2. Name of the investigator with the FCOI.

5.9.3.3. Name of the entity with which the Investigator has the FCOI.

5.9.3.4. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium).

5.9.3.5. Value of the financial interest.

5.10. Committee Documents and Record Retention

5.10.1. All committee meetings and communications will be recorded in writing.

5.10.2. All decisions regarding review of financial disclosures and determinations of FCOI and management plans will also be recorded in writing.

5.10.3. All such committee documents will be retained by MHC HRPP, in accordance with *MHC_RP0114_IRB Documentation and Research Record Retention Policy.*

5.11. Education and Training

5.11.1. All investigators required to adhere to this policy must complete financial conflict of interest training via Collaborative Institutional Training Initiative (CITI Program). Training will include the following topics:

5.11.1.1. Financial Conflict of Interest: Overview, Investigator Responsibilities and COI Rules

5.11.1.2. Institutional Responsibility as they affect Investigator.

5.11.1.3. Conflict of Commitment, Conscience, and Institutional Conflict of Interest.

5.11.2. Training will be required at least every 4-years and immediately in the event of any of the following:

5.11.2.1. McLaren Health Care FCOI policies change in a manner that affects Investigator disclosure/compliance requirements.

5.11.2.2. An investigator is new to McLaren Health Care and its subsidiary organizations.

5.11.2.3. An investigator is found to be non-compliant with this policy or a specific management plan.

5.11.3. Consistent with federal regulations, researchers involved in PHS funded research will be required to complete a training course specific to PHS requirements. The training must be completed prior to engaging in PHS funded research and at least every four (4) years thereafter.

5.11.3.1. The CITI Program, COI Basic course required for all investigators at MHC, is designed to satisfy training requirements associated with the U.S. Public Health Service (PHS) regulations on financial conflicts of interest.

6. References:

6.1. 21 CFR Part 54

6.2. 45 CFR Part 50, Subpart F

6.3. 45 CFR Part 94

6.4. Public Health Service (PHS) Regulations

6.5. MHC HRPP Conflict of Interest Submission Process

6.6. MHC_RP0114_IRB Documentation and Research Record Retention

6.7. MHC_CC0137_Provider Conflict of Interest and Business Integrity

6.8. MHC_CC0123_Non-Compliance in Human Subject Research

7. Previous Revisions: 3/24/13, 2/15/16, 12/15/21, 2/1/23

8. Supersedes Policy: Previously - Review and Management of Conflict of Interest in Research was identified as MHC_RP0202, now its new number is MHC_RP0203

9. Approvals:

Research Conflict of Interest Committee initial approval: 3/14/13
Research Conflict of Interest Committee acknowledgement: 2/26/16, 4/14/16

Signature on File *3/22/2024*

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